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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,327	08/29/2001	Swaminathan Jayaraman	638.45	6222
33771	7590	11/17/2004	EXAMINER	
PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 601 BRICKELL KEY DRIVE, SUITE 404 MIAMI, FL 33131			BUI, VY Q	
		ART UNIT	PAPER NUMBER	
		3731		

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/941,327	JAYARAMAN, SWAMINATHAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Vy Q. Bui	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 August 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2,12-15,17,23-27 and 29-37 is/are pending in the application.  
 4a) Of the above claim(s) 12,17,27,30 and 32-36 is/are withdrawn from consideration.  
 5) Claim(s) 23-26,29 and 31 is/are allowed.  
 6) Claim(s) 1-2, 13-15 and 37 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4)  Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)  
 6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 12, 17, 27, 30, 32-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/20/2004.

The Applicant argued that all distinct inventions in the present application should be examined because this would not cause a serious burden for the Examiner. The Examiner would like to examine all the distinct inventions in the invention. However, time constraint does not allow the Examiner to do so.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 13-15, 29, 31 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over PENN et al. (6,375,677) in view of CALLOL et al. (6, 174,329).

As to claims 1-2, 14, 29 and 31, PENN discloses substantially all the limitations in the claims, including a biological material/medicinal composition to reduce thrombogenicity of the stent or to provide anticoagulation action (so as to avoid restenosis). PENN does not explicitly disclose two layers of coatings not more than 10 microns. CALLOL

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having an inner coating layer of a thickness from 0.01 to 25 microns and an outer coating layer of a thickness from 1.0 to 50 microns. Because there is no specific name for a biological substance in the claim, inner and outer layers of the coatings, which are of biological compatible substances and therefore can be considered in a broad sense as biological substances. Notice that inherently, one of ordinary skill in the art can recognize that the drug concentration in a coating layer of a stent must have some variation along the stent, because there is no need to make the drug concentration in the coating layer a constant number without some minor variation.

As to claim 13, PENN and CALLOL do not disclose both coatings are of a radiopaque substance. However, it is just a matter of design choice to have two coatings of a radiopaque material.

As to claim 15, PENN and CALLOL do not disclose both coatings are of a polymeric substance. However, it is just a matter of design choice to have two coatings of a polymeric substance.

As to claim 37, increasing a thickness of a stent at the end portions to increase radial rigidity of the stent is well known. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the PENN or CALLOL stent to have thicker end portions so as to increase radial rigidity of the stent.

***Allowable Subject Matter***

Claims 23-26 and 29, 31 are allowed.

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***Response to Arguments***

Applicant's arguments with respect to claims 1 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2158. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*VQ Bui*

*11/15/2004*

Vy Q. Bui  
Primary Examiner  
Art Unit 3731